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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/074,247	02/14/2002	Lawrence M. Nugge	001107.00229	5075

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EXAMINER

SWITZER, JULIET CAROLINE

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 05/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/074,247

Applicant(s)

NOGEE ET AL.

Examiner

Juliet C. Switzer

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-58 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-58 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s): ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-8, 17-18, 21-23, drawn to compositions comprising antibodies, classified in class 530, subclass 387.1.
 - II. Claims 9-17, 19, 21-23, drawn to compositions comprising nucleic acid probes, classified in class 536, subclass 24.32.
 - III. Claims 24-33, 36, 37-46, drawn to methods for detecting a predisposition for lung disease which utilize antibodies, classified in class 435, subclass 7.1.
 - IV. Claims 24-31, 34-44, 47-48, drawn to methods for detecting a predisposition for lung disease which utilize nucleic acid probes, classified in class 435, subclass 6.
 - V. Claims 49-58, drawn to methods for predicting lung disease patient's response to therapeutic intervention, classified in class 435, subclass 6 or 435/7.1.

Further Restriction Applied to Each Group

Each group detailed above reads on more than one patentably distinct group, wherein each of the distinct group is drawn to compositions of antibodies or nucleic acids specific for independent polymorphisms, methods for the diagnosing disease using the different antibodies or nucleic acids, or methods for predicting patient response to treatment focusing on different polymorphisms. For example, group I above encompasses fifteen different inventions, that is, antibody compositions specific for each of the specific polymorphisms recited. For the elected group (of groups I-V), applicants must further elect single polymorphism for examination in the

appropriate product or method claim. For example, if applicant elects group I, applicant should further elect one of the polymorphisms for examination.

It is noted that many of the groups contain claims that are generic with respect to the particular polymorphism. These will be examined for their full scope, but within each group, claims that recite specific polymorphisms will be examined only with respect to the elected polymorphism. It is also noted that claims 21-23, 29-31, 42-44, and 54-56 all recite a single polymorphism. If this polymorphism is not the elected polymorphism, these claims will be withdrawn from prosecution. Applicant is advised that examination will be restricted to only the elected polymorphism and should not to be construed as a species election. Prior to allowance, non-elected subject matter will be required to be deleted from any allowable claims.

The inventions are distinct, each from the other because of the following reasons:

The inventions of Groups I and II are patentably distinct because they are drawn to different products having different structures and functions. The antibody of Group I is composed of amino acids linked in peptide bonds and arranged spatially in a very specific tertiary structure that allows that antibody to specifically bind to particular regions, i.e. epitopes, of the encoded polypeptide. Further, antibodies are glycosylated and their tertiary structure is unique, where four subunits (2 light chains and 2 heavy chains) associated via disulfide bonds into a Y-shaped symmetric dimer. The nucleic acid of Group II is composed of nucleotides linked in phosphodiester bonds and arranged in space as a double helix. Furthermore, the products of Groups I and II can be used in materially different processes, for example, the DNA

of Group II can be used in hybridization assays and the antibody of Group I can be used in immunoassay or to purify proteins. Consequently, the reagents, reaction conditions, and reaction parameters required to make or use each invention are different. Therefore, the inventions of Groups I and II are patentably distinct from each other.

2. Inventions I and III and inventions I and V and inventions II and IV and inventions II and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies of invention I and the nucleic acids of invention II each can be used in a wide variety of methods. For example, the antibodies can be used for protein purification, and the nucleic acids can be used in amplification assays. In addition, both products can be used in the two distinct methods recited herein.

3. Inventions I and IV and inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions the antibodies of invention I are not disclosed for use in the methods of invention IV, and likewise, the nucleic acids of invention II are not disclosed for use in invention III.

4. Inventions III, IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the

different inventions are drawn to methods which either have different modes of operation (the methods of group III operate using antibodies while the methods of group IV operate using nucleic acids) or have different functions and effects (the methods of groups III and IV are directed towards identifying a predisposition for disease while the methods of group V are directed towards predicting a response to intervention).

5. With regard to the restriction between individual antibodies or nucleic acid sequences, each is patentably distinct because they are unrelated molecules, i.e. these antibodies and nucleic acids are unrelated because they do not share a common structure as each is specifically designated as being able to detect a separate and distinct polymorphism. A reference against one would not anticipate or obviate another, and thus for each particular sequence a separate search of the patent and non-patent literature is required. These separate searches would impose undue burden on the examiner.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as demonstrated by their different classification and recognized divergent subject matter and because inventions I-V require different searches that are not cointensive, examination of these claims would pose a serious burden on the examiner and therefore restriction for examination purposes as indicated is proper.

7. A telephone call was made to Lisa Hemmendinger on 5/9/03 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C. Switzer whose telephone number is (703) 306-5824. The examiner can normally be reached on Monday through Friday, from 9:00 AM until 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Juliet C. Switzer
Examiner
Art Unit 1634

May 12, 2003



W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600